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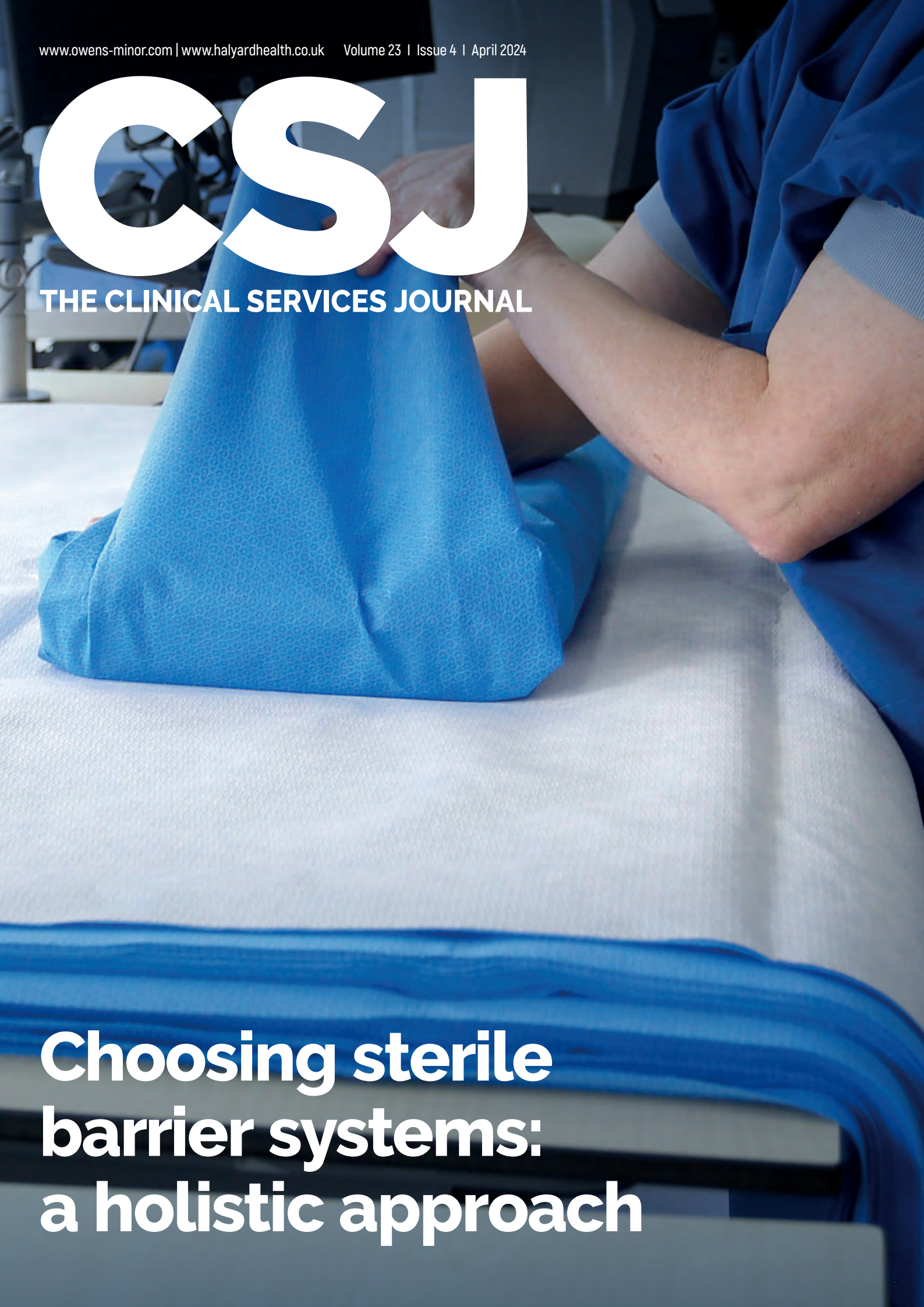

Choosing sterile barrier systems: a holistic approach

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As the healthcare sector faces increasing pressure to reduce its environmental impact, sterile services departments are debating the relative advantages of flexible sterile wrap *versus* reusable rigid containers. Choosing a sterile barrier system is a major decision and can only be made after weighing all the relevant factors. **Karina Engels** provides an insight into the key considerations.

While sustainability is important and should be part of the design of any sterile barrier system, it cannot be the only factor considered when choosing sterile packaging systems. One must also consider such factors as usability, space, costs and, above all else, patient safety.

When it comes to choosing the right sterile packaging system, patient safety must be the primary determining factor. The European Centre for Disease and Control (ECDC) estimated that in the period from 2016 to 2017, 3.1 to 4.6 million people acquired a healthcare-associated infection (HCAI) during that period, in acute care hospitals, in EU/EEA countries.[1] HCAIs can lead to increases in patient morbidity and mortality, with more than 90,000 people dying every year in the EU/EEA due to the six most common infections in healthcare settings.[2] Furthermore, HCAIs account for a significant cost to the healthcare sector, representing up to 6% of public hospital budgets.[3]

Comparing the risk for a barrier breach

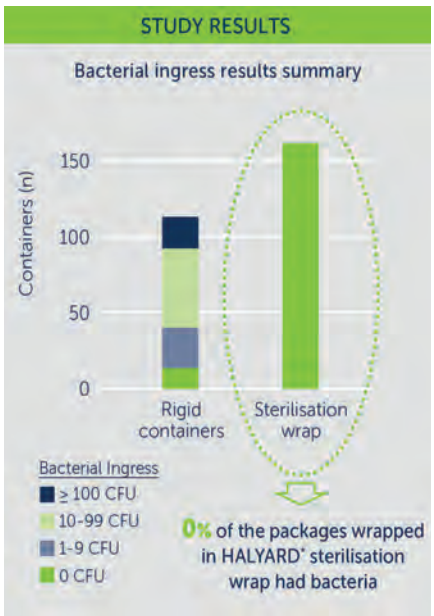
Maintaining a sterile environment starts with sterile barrier systems (SBS). Various methods are used for sterilising surgical instruments. SBSs are used to enclose and maintain the sterility of instruments until the point of use and to allow for aseptic presentation.[4] SBSs include heat sealable pouches, synthetic disposable wraps and rigid containers.

Unfortunately, SBSs aren't a bulletproof solution. For example, with wrapped trays, stacking, sliding, transporting or using improper folding techniques can result in barrier breaches – breaches through which bacteria could enter.

For rigid containers, bacteria could enter via breaches caused by poorly joined, oxidised, cut or compressed gaskets; gaps caused by mismatched lids and bases; loose filter retainers; loose rivets or fasteners; or due to misuse, damage or age-related fatigue. Furthermore, the aluminium body of most rigid containers can become degraded from the use of incompatible detergents, incorrect pH or repeated metal-on-metal rubbing during cleaning.[5]

A HALYARD-sponsored study conducted by Applied Research Associates (ARA), an independent international research laboratory (the "Shaffer Study"), used a dynamic biological aerosol test to evaluate the ability of an SBS to maintain the sterility of surgical instruments, devices and implants.[6] Using a custom aerosol chamber, the Shaffer Study challenged 111 rigid containers of various durations of use (unused, used <5 years, used 5-9 years) and 161 wrapped trays using three grades of sterilisation wrap with ~102 colony-forming units per litre of air containing aerosolised *Micrococcus luteus* with a count median particle size of 1 µm. The SBS simultaneously experienced air volume exchanges caused by vacuum cycles that simulated air exchange events occurring during the sterilisation, transportation and storage of sterilised instrument trays in healthcare facilities.

The Shaffer Study, which was published in the *American Journal of Infection Control (AJIC)* in 2015, found that sterilised wrapped trays demonstrated significantly greater protection than sterilised rigid containers against the ingress of airborne bacteria. Of the 111 rigid containers tested, 97 (87%) demonstrated bacterial ingress into the container. By comparison, none of the 161 wrapped trays demonstrated bacteria ingress into the tray.[7] The Shaffer Study further showed that contamination rates of rigid containers increased significantly with increasing duration of use. Specifically, the study found that the seals of the rigid containers aged and lost some elasticity compared to new seal material. They



also sustained nicks, cuts and creasing after years of use.

Furthermore, data collected during the Shaffer Study suggest that the duration of use for rigid containers was at least partially accountable for their compromised ability to maintain the sterility of their contents under the defined test conditions compared to sterilisation wraps. This is particularly concerning because all the tested containers were new or identified as clinically acceptable containers. In fact, some of the rigid containers tested, even though identified and deemed 'acceptable' and 'in use' by the supplying healthcare facility, had loose filter housings, mismatched lids/bottoms or dents/nicks on the lids/bottoms. Perhaps even more concerning is that 72% of the unused containers showed various levels of bacterial ingress.[8]

Does your SBS perform as expected?

All of this highlights the importance of evaluating whether an SBS performs as expected. For sterilisation wrap, the process is quite simple: one only needs to conduct a visual inspection of the wrap after the packaging is opened. However, for sterilisation containers, the process can be a bit more complex.

For example, to help end-users properly evaluate their sterilisation containers, the Association Française de Normalisation (AFNOR) developed a 'water test' to determine whether a sterilisation container can be used 'as is'.[9] The test requires one to fill the container with 5mm of water. Once filled, the container is to be closed and placed on its side for a period of 30 seconds, during which time one is to inspect all four sides for signs of a potential leak.

The AFNOR test was published after a multicentric survey conducted across seven French hospitals showed that 29% of all tested sterilisation containers leaked[10] – leakage that a paper published by CH Métropole Savoie has linked to a potential risk of bacterial ingress (the "Savoie Study").[11] In the Savoie Study, researchers used an aerosol with *Micrococcus luteus* and overpressure (25, 50 or 75 millibar) to simulate atmospheric pressure variations. What they found was that, at 25 millibar, 74% of the containers that leaked during an AFNOR water test were also prone to bacterial ingress. This led the authors to conclude that the water test was a valuable tool for evaluating the effectiveness of a sterilisation container.[12]

Image courtesy of Van Straten Medical

Go Jack instrument opener made from recycled sterilisation wrap (manufactured by Van Straten Medical and endorsed by GreenCycl.)

When it comes to sustainability, the answer is not clear

Aside from patient safety, sustainability and cost are major decision-making factors in the SBS purchasing process. The former is being driven by the EU Green Deal, which aims to make Europe the first climate-neutral continent by 2050. Such sustainability-minded initiatives are having a direct impact on healthcare purchasing. For instance, inspired by the EU Green Deal, the Netherlands launched a voluntary Green Deal in Care initiative. Signed by more than 300[13] healthcare-related parties, the signatories pledge to reduce their carbon footprint and to implement socially responsible and circular procurement practices. While such initiatives are laudable, they will only achieve their intended goals when purchasing decisions are based on facts, local feasibility studies and the evaluation of recycling programmes.

While there is no arguing that different sterile barrier systems have different carbon footprints, the actual size or scale of the difference remains open for debate.

For example, one study (the "Friedericy Study") claims that the carbon footprint of reusable rigid containers is 85% less than that of single-use tray wraps, with a significantly lower carbon estimate for reusable rigid containers (57g CO_2e per use).[14]

To reach this conclusion, the Friedericy Study compares the environmental gain after 5000 cycles for flexible sterilisation wrap *versus* sterilisation containers and looks at the breakeven point of both packaging systems. However, this choice of benchmark is questionable considering that CEN standard EN 868-8[15] sets 500 cycles as the minimum service life for sterilisation containers. If a container is assumed to be used 120 times a year, which is the figure used in a study published in the Health Economics Review (the "Krohn Study"),[16] then, when considered against the lifespan of 5000 cycles set out in the Friedericy Study, the result would seem to assume that containers could be used without replacement for approximately 41 years.

The Friedericy Study[17] cites a waste of 12kg of plastic per surgical procedure meaning blue wrap would represent 11.5% of that procedure's total plastic waste. However, our calculations show that H300 sterilisation wrap (101x101cm), the reference wrap in the Friedericy study, would represent 2.43% of the procedural plastic waste (when three instrument trays are unwrapped).[18] The Friedericy Study's Lifecycle Assessment[19] includes the washing and disinfecting of the containers. However, it is unclear whether the wastewater treatment associated with washing the containers is included in this calculation.

A recent *Green Surgery Report* published by the UK Health Alliance on Climate Change[20] helps fill in some of these blanks, particularly ▶

Making an informed sterile barrier system purchasing decision starts with knowing *all* the facts, and the fact is that both sterilisation wrap products and rigid containers have their own pros and cons.

as to energy consumption. The report refers to a study published by Rizan *et al.*[21] that looked at minimising the carbon footprint and the financial costs of the steam sterilisation and packaging of reusable surgical instruments. The Rizan paper was published in the *British Journal of Surgery* (BJS), one of the top six[22] periodicals in the world (the "Rizan Study").

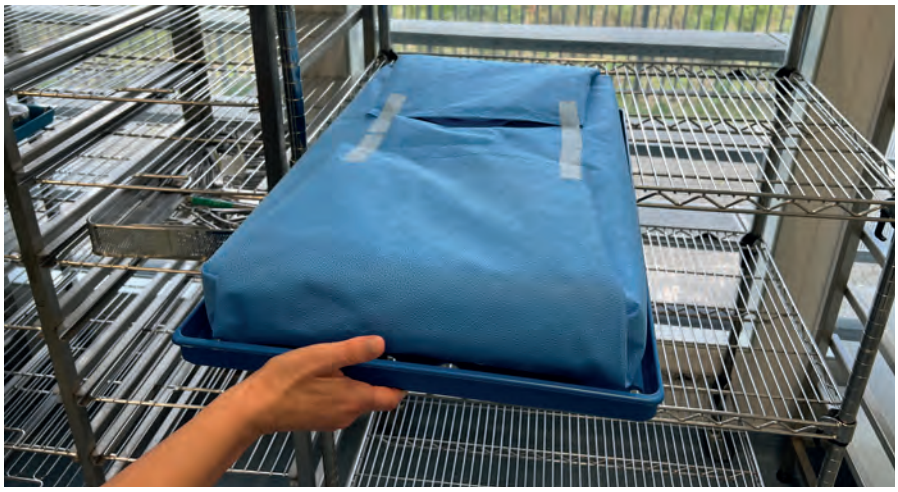
The Rizan Study unequivocally found that the carbon footprint of reusable rigid containers is higher than that of single-use tray wraps (721g CO_2e per set for containers *vs* 387g CO_2e per set for flexible wrap).[23] According to the Rizan Study, this is principally due to the additional washing required for rigid containers (which is inefficient due to their bulkiness). On average, it is accepted that 10 litres of water per container per washing cycle is used.

By no means are we saying that the carbon footprint of sterile wraps is better than that of reusable rigid containers but that calculating a product's actual footprint can vary according to the database, method and reporting used.

Calculating costs

Another key factor that drives any purchasing decision is costs – and SBS are no exception. In fact, according to the Krohn Study, hospitals should monitor the costs of all direct and indirect processes to achieve efficiency and safeguard financial sustainability.[24] One neglected process with significant costs is the processing of reusable medical devices and their packaging performed in the central sterilisation supply department (CSSD) and the operating theatre. Looking at the real cost of reprocessing and sterilising surgical instruments, the Krohn Study concluded that sequential packaging results in the highest cost (EUR 3.87), followed by one-step sterilisation wrap packaging (EUR 3.44). The lowest cost was allocated to reusable containers without inner wrap (EUR 2.05).[25] However, such an analysis fails to consider the costs of maintaining reusable sterilisation containers which, following EN 868-8, should be done every 100 cycles.[26] According to researchers at the Hôpital Pitié-Salpêtrière, the costs of such preventative maintenance is estimated to be around EUR 72 per container.[27]

Researchers at the Hôpital Pitié-Salpêtrière also evaluated the costs of maintaining 3,900 containers *versus* the cost of replacing them with flexible packaging. What they found was that the use of flexible packaging resulted in annual savings of EUR 19,356 starting from the second year onwards.[28] This finding has been confirmed in a paper by Diallo *et al*, which found that the higher cost of reusable containers stems not from the initial investment, but from the amount of manual work required to properly maintain them.[29]



Space and user friendliness

While patient safety, sustainability and costs are often the main driving factors behind one's SBS purchasing decisions, other factors – including space – should be considered as well. One manufacturer of storage units for sterilised products has calculated that sterilisation wraps, with appropriate storage like a basket-in-basket system, require 50% less space within the CSSD than their reusable rigid container counterparts.[30] Another very important element to consider is feasibility and staff satisfaction. A simple survey conducted at the L'Hôpital FOCH[31] found that 47% of CSSD staff were satisfied with sterilisation wrap, compared to 25% with containers. The surveyed workers specifically noted flexible packaging's ease of use, comparative lightness and decreased risk for burns when unloading the sterilisers.

That same survey found that 42% of operating theatre staff preferred containers compared to 26% who preferred sterlisation wraps, with many expressing their belief that containers are easier to store and require less precaution. The study does not indicate whether the staff were storing the containers in accordance with EN 868-8[32] which states that containers should only be stacked two high.

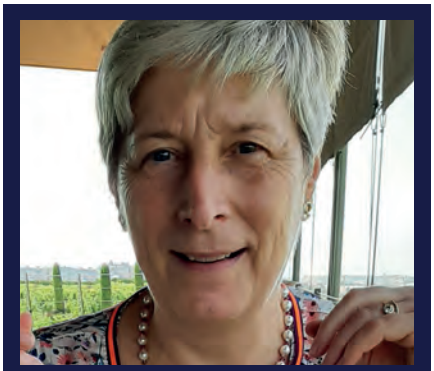
A win-win-win

Making an informed SBS purchasing decision starts with knowing *all* the facts, and the fact is that both sterilisation wrap products and rigid containers have their own pros and cons.

For instance, while reusable containers require regular maintenance, inspection and washing, flexible packaging needs to be inspected carefully. Furthermore, while properly using containers requires that a facility have the staff, space and budget, the use of flexible sterilisation wrap also comes with its own infrastructure demands.

As such, the debate should not be about which packaging is best but about how we can make both options better. This means helping and training end users to identify and separate materials that can be recycled. It also means working with waste management companies to spark their interest to set up collection and recycling schedules.

If we do this, then both flexible wrap and rigid containers can be a viable way to help reduce one's environmental footprint without sacrificing patient safety, impacting employee wellbeing, or making a significant capital investment – which, in our book, is what we call a win-win-win. **CSJ**



About the author

Karina Engels works as a Consultant Product Manager, Sterilisation, at O&M HALYARD. Karina trained as a general nurse and worked in Bordet Institute in Brussels; after which, she went into medical sales and product management. As Product Manager for sterilisation products, Karina has been a member of Edana (non-woven manufacturers) and DIN TC198/WG7. More recently, she represented HALYARD in the environmental working group of the SBA. She initiated a sterilisation wrap recycling pilot study in 2018 and is passionate about bringing recycling solutions and new technologies to end-users.

References: Choosing Sterile Barrier Systems: a more holistic approach

1. Suetens, C. et al. (2018), Prevalence of healthcare-associated infections, estimated incidence and composite antimicrobial resistance index in acute care hospitals and long-term care facilities: results from two European point prevalence surveys, 2016 to 2017, Eurosurveillance, Vol. 23/46, https://doi.org/10.2807/1560-7917.es.2018.23.46.1800516 .
2. Cassini, A. et al. (2016), Burden of Six Healthcare-Associated Infections on European Population Health: Estimating Incidence-Based Disability-Adjusted Life Years through a Population Prevalence-Based Modelling Study, PLOS Medicine, Vol. 13/10, p. e1002150, https://doi.org/10.1371/journal.pmed.1002150 .
3. Slawomirski, L. et al (2017), The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level, OECD Health Working Papers, No. 96, OECD Publishing, Paris, https://doi.org/10.1787/5a9858cd-en .
4. EN ISO 11607 – 1: 2020. Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier systems and packaging systems. ISO - International Organization for Standardization
5. Shaffer H. et al. Sterility maintenance study: Dynamic evaluation of sterilized rigid containers and wrapped instrument trays to prevent bacterial ingress, American Journal of Infection Control 43 (2015) 1336-41 page 1337.https://doi.org/10.1016/j.ajic.2015.07.010
6. Ibid, page 1337.
7. Ibid, page 1339.
8. Ibid, page 1340.
9. FD S98-053:2014-07-02. Test protocole to perform on reusable sterile barrier systems (containers) in order to evaluate the impermeability of the vat/lid closure. https://standardstore.afnor.org/en-gb/standards
10. B. Valence, J. Molina. Validation of the packages in a central hospital sterilization - National Workshop Days for Sterilization Studies. Marseille 2013
11. Decarout et al. Évaluation de l'intérêt du test de fuite à l'eau pour le contrôle de fonctionnalité des conteneurs de stérilisation, Annales Pharmaceutiques Françaises (2018) 76, 464—472, page 465.
12. Ibid, page 471.
13. Green deal_C238: Green Deal overeenkomsten (greendeals.nl)
14. Friedericy, H.J.; van Egmond, C.W.; Vogtländer, J.G.; van der Eijk, A.C.; Jansen, F.W. Reducing the Environmental Impact of Sterilization Packaging for Surgical Instruments in the Operating Room: A Comparative Life Cycle Assessment of Disposable versus Reusable Systems. Sustainability 2022, 14, 430. https://doi.org/10.3390/su14010430
15. EN 868-8: Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods (en-standard.eu)
16. Krohn et al. Analysis of processes and costs of alternative packaging options of sterile goods in hospitals – a case study in two German hospitals, Health Economics Review 2019. https://doi.org/10.1186/s13561-018-0218-2
17. Friedericy, H.J.; van Egmond, C.W.; Vogtländer, J.G.; van der Eijk, A.C.; Jansen, F.W. Reducing the Environmental Impact of Sterilization Packaging for Surgical Instruments in the Operating Room:

A Comparative Life Cycle Assessment of Disposable versus Reusable Systems. Sustainability 2022, 14, 430. https://doi.org/10.3390/su14010430

18. H300, 101x101cm = 97.2gr/sheet, 3 trays used (291gr): represents 2.43% of 12kg plastic waste/procedure. When heavier grades or more instrument trays are used, this percentage will increase.
19. Friedericy, H.J.; van Egmond, C.W.; Vogtländer, J.G.; van der Eijk, A.C.; Jansen, F.W. Reducing the Environmental Impact of Sterilization Packaging for Surgical Instruments in the Operating Room: A Comparative Life Cycle Assessment of Disposable versus Reusable Systems. Sustainability 2022, 14, 430. https://doi.org/10.3390/su14010430
20. Brighton & Sussex Medical School, Centre for Sustainable Healthcare, and UK Health Alliance on Climate Change (2023). Green surgery: Reducing the environmental impact of surgical care. London: UKHACC. https://ukhealthalliance.org/sustainable-healthcare/green-surgery-report/
21. Rizan C. et al. Minimizing carbon and financial costs of steam sterilization and packaging of reusable surgical instruments. British Journal of Surgery, 2022, 200 – 2010, https://doi.org/10.1093/bjs/znab406
22. Overview - BJS (British Journal of Surgery) - Wiley Online Library: https://bjssjournals.onlinelibrary.wiley.com/hub/journal/13652168/productinformation.html#:~:text=Aims%20and%20Scope%20With%20an%20impa
23. Rizan C. et al. Minimizing carbon and financial costs of steam sterilization and packaging of reusable surgical instruments. British Journal of Surgery, 2022, 200 – 210, page 205 https://doi.org/10.1093/bjs/znab406
24. Krohn et al. Analysis of processes and costs of alternative packaging options of sterile goods in hospitals – a case study in two German hospitals, Health Economics Review 2019. https://doi.org/10.1186/s13561-018-0218-2, page 1.
25. Krohn et al. Analysis of processes and costs of alternative packaging options of sterile goods in hospitals – a case study in two German hospitals, Health Economics Review 2019. https://doi.org/10.1186/s13561-018-0218-2.
26. EN 868-8: Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods (en-standard.eu)
27. Laincer et al. Prérequis à la mise en place d'un emballage usage unique résistant en remplacement des conteneurs au sein de trois blocs opératoires : analyse d'impact budgétaire. Presented SF2S congress, September 2023. https://www.formations-hopscotch-congres.com/_files/ugd/331178_5a6b2dfa01114054968aaec19c97abb1.pdf See slide 14:
28. Ibid, slide 16.
29. Diallo et al. Conditionnement des instruments de chirurgie sterilisés à la vapeur d'eau en milieu hospitalier: comparaison des conteneurs et des feuilles d'emballage à usage unique. Stérilisation Centrale 2/2017
30. Belintra Inc. Efficiency of Belintra UBeFlex® Open Storage vs. Chrome Wire Storage. 2017Jan. Used with the express permission of Belintra, Inc, 2017.02.03_Belintra_vs_Chrome-Wire-Storage_Imperial.pdf
31. Diallo et al. Conditionnement des instruments de chirurgie sterilisés à la vapeur d'eau en milieu hospitalier: comparaison des conteneurs et des feuilles d'emballage à usage unique. Stérilisation Centrale 2/2017

32. EN 868-8: Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods (en-standard.eu)